BRITISH GENERIC MANUFACTURERS ASSOCIATION

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Health and Sport Committee – Supply and Demand for Medicines

Many thanks for your letter of 5 February seeking a response to these two further questions of the Committee following the hearing on 21 January, to which I was grateful to be invited:

1. What are the main barriers to entry in the generic market?
2. How can greater competition in the generics market be encouraged?

I'll take the two questions in turn.

What are the main barriers to entry in the generic market?

Compared with many other European countries, there are very few barriers to entry to the UK market. Once an unbranded generic medicine has received its marketing authorisation from the MHRA, the Marketing Authorisation Holder (MAH) is able to launch the product without further official approvals.

Other European countries require further approvals, such as for the price to be charged, reimbursement, and substitution status. All of these are automatic in the UK with the result that the launch of a generic medicine in the UK typically takes place before launch in other European countries.

Product launch may be frustrated by legal action by the originator company alleging infringement of their intellectual property rights. This does not impact the grant of the MA, but may delay launch of the generic if the originator seeks and is granted an interim injunction preventing launch whilst the legal case continues.

Once on the market, upstream constraints on supply generally relate to availability of raw materials and Active Pharmaceutical Ingredients (API) from external suppliers for the manufacture of finished dosage form product; whilst downstream constraints are essentially commercial in nature, relating to price competition, increased costs of goods or due to regulatory change, or secondary care tender processes and associated penalties for non-supply.

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How can greater competition in the generics market be encouraged?

It is important to recognise that there are already high levels of competition in the generic industry in the UK. Over 94% by volume of generic medicines dispensed in the UK fall within Category M of the English Drug Tariff. Category M is defined as applying to "Drugs which are readily available", and typically includes products where:

- there is more than one generic manufacturer; and
- the reported net ingredient cost (ie cost to the NHS) is more than £1m and more than 50,000 items are dispensed annually in England; or
- more than 200,000 items are dispensed annually in England.

It is this Category of the Drug Tariff where the reimbursement price paid by the NHS is based on manufacturers' actual net sales price, itself constrained by competition.

Whilst a similar number of products is listed in Category A, the volume they represent is less than 6% of the whole. Clearly, competition will be less effective for these products where the size of the market is smaller and there are fewer suppliers. Reimbursement prices for these products are based on the list prices of two specific manufacturers (which may or may not market the product concerned) and two specific wholesalers, the latter weighted twice. The Department of Health and Social Care (DHSC) in England is currently consulting on changing this mechanism such that Category A reimbursement prices would also be based on manufacturers' actual net sales price. This would ensure that prices paid by the NHS are more reflective of the manufacturer's actual net selling price.

During your Committee's hearing on 21 January, I said that the DHSC in England had discussed with us means of introducing competition on specific products where it is currently lacking, but that we had yet to find what we believe would be an effective means of doing this. At issue here is whether, for these very small products, there is a sufficiently sized market for competition to be sustained.

Rather than intervention in the market, which could have unintended consequences, there may be scope for the MHRA in some way to streamline the approvals process—the one clear barrier to market entry—for defined categories of product to reduce the time in getting to the market and the costs of doing so.

We shall continue our discussions with DHSC in the hope of finding a mechanism that would work. However, our overarching view is that it is wrong to have different pricing and reimbursement mechanisms for unbranded and branded medicines: rather, we should have different mechanisms for products that face competition and those that don't.

Outcomes and value-based pricing

Your letter also noted that outcomes and value-based pricing was mentioned during the hearing, and you asked for the BGMA's perspective on what should happen if the outcomes (based on the patient's experience of taking the medicine), once assessed, differ from the original claims by the drug manufacturer.

These are much more matters for the ABPI than the BGMA. Our members only come to the market once the originator company's intellectual property protection has lapsed, typically after 15 years. By that time, there will be a large amount of real-world data on the relative efficacy of the product and any further assessment beyond the original SMC work will have long been done.

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We should be concerned, however, if the operation of an outcomes and value-based pricing system were to add complexity and uncertainly to the generics market. For example, any differentiation that led to segmentation of the market would weaken the effectiveness of the generic business model.

Summary

The data show that Scotland and the rest of the UK enjoy the lowest priced generics in Europe as evidenced by the Oxera study to which we referred, and suffer from amongst the lowest levels of medicines shortages. These benefits are due to low barriers to market entry and low levels of official intervention in the market.

Whilst we acknowledge and understand concern about the prices of a small number of specific products, we are concerned that misplaced intervention in the market could disrupt the benefits that the NHS and patients enjoy.

I hope that this letter clarifies the points in which the Committee was interested, but we should, of course, be very happy to contribute further if that were to be helpful.

With best wishes

Warwick Smith
Director General